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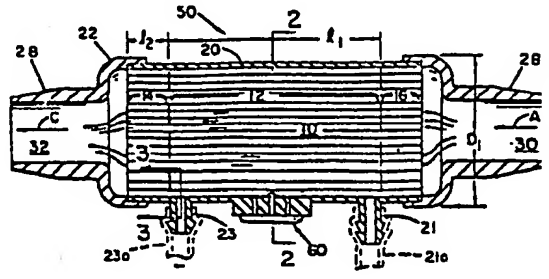
(54) **Nested hollow fiber humidifier.**

(57) A humidifier for inhalated air comprising a nest (10) of air-transmitting hollow fibers connected in parallel by inlet (30) and outlet (32) connections said fibers having walls of substance permeable to water vapor and impermeable to liquid water and a water-filled chamber (20) surrounding the fibers which divide inhalation air into a series of air-flow filaments, for humidification by water vapor that permeates the walls of the fibers said humidifier built in a practical, fail-safe, low flow resistance compact unit that can be disposable.

FIG 1



EP 0 009 543 A1

EU 835

NESTED HOLLOW FIBER HUMIDIFIER

Background of the Invention

This invention relates to a humidifier for humidifying and delivering gases such as air or oxygen directly to a patient or to a person in good health. It constitutes an improvement over my prior patents U.S. 3,616,796; 3,871,373; 3,912,795 and to later efforts of Dobritz, U.S. 4,010,748 and 4,086,305.

According to my prior patents, a new type of medical humidifier is provided which operates according to the diffusion principle in which water vapor from a water supply permeates a wall or membrane and enters a stream of breathing air while the water supply is maintained separate from the air stream by the wall. Such a diffusion humidifier offers a number of potential advantages over other methods of humidification, but no satisfactory form for its manufacture has been found. To be suitable for production and wide use I have recognized that numerous difficult criteria should be met. As the humidifier is to be connected directly to the airway of a patient and life-supporting air is to be channeled through it, it should have low air-flow resistance, preferably so low that the patient can breath through the humidifier without assistance (e.g. with a flow resistance comparable to a standard endotracheal tube). It should be capable of fail-safe operation to avoid any substantial risk that the patient might

inhale large volumes of gross (i.e. liquid) water. It should be of small size to avoid introducing a large compressible air volume in the path and to enable placement close to the mouth, for example as a tubular component of a breathing circuit. It should have a long shelf life. And it should be of simple and rugged construction and of such low cost as to be disposable.

Hollow fibers with walls of water-permeable substance have been used for many years in filters and the like, see e.g. U.S. patents 3,228,877, 3,339,341 and 3,342,729

In the context of a heat exchanger, U. S. patent 4,098,852 has suggested to condition or humidify air by use of fibers. But the structure employed fails to meet many of the essential criteria.

Summary of the Invention

According to the invention a humidifier is provided for a respiratory flow path connected to the airway of a patient, through which life-supporting air can be channeled, comprising a compact nest of discrete, elongated air-transmitting, hollow, relative large bore, relative thin wall fibers connected in parallel by inlet and outlet connections and having wall substance permeable to water vapor and impermeable under operating conditions to liquid water. The fibers are arranged to divide dry inhalation air (here the word "air" is intended to include pure or diluted oxygen) for a patient, into a series of air-flow

filaments for humidification by water vapor that permeates walls of the fibers from surrounding water. The fibers are provided in size and number sufficient to freely pass under normal air-flow conditions an aggregate air flow volume corresponding to the life-supporting need of the patient and to provide effective fiber surface area sized to pass water vapor to humidify substantially to saturation this air at normal flow rates from water heated to about body temperature. An outlet connection is arranged to collect the thus-humidified filaments of air and direct the unified flow into the patient. By this means a humidifier is provided which can achieve full humidification of air directed into a patient in a practical, low flow-resistance, compact unit that can be disposable.

According to important further aspects of the invention rigid means such as a rigid wall define a relatively negative-pressure water-filled chamber surrounding the effective lengths of the fibers; a pressure relief valve is connected to the water side of the unit, constructed to vent to the atmosphere in the event of any condition tending to produce a positive pressure in the water that surrounds the fibers; the substance of the fibers has dry stability and a transmission characteristic of the order of one pound of water per square foot of fiber wall area per .005 inch wall thickness, per hour, when subjected to test with water at 37.5°C, at 2 psi negative

pressure disposed on the exterior of fibers, and with a flow of anhydrous oxygen at rate of 200 liters per minute introduced to flow in parallel through a nest of fibers of about 5 inches length; the aggregate air humidifying capacity of the fibers is of the order of 50 liters per minute flow rate or higher; the fibers have an aggregate air flow capacity between about 180 and 450 liters per minute with an air pressure drop of 5 cm water from end to end of the hollow fibers; the fibers define an aggregate effective water vapor transmitting surface area of the order of about 1/2 square foot; the hollow fibers have wall thickness that is 10% or less of the internal diameter of the fibers; the fibers have an internal diameter greater than .050 inch and less than .070 inch; the substance of the fibers is selected from the group consisting of polysulfones and acrylic co-polymers; the substance of the fibers incorporates a wetting agent, preferably glycerine or sodium sulfo succinate; and water inlet and outlet conduits that provide a flow of heated water over the exterior of the fibers are rigid to resist collapse when vacuum is applied, the inlet conduit is a suction line adapted for connection to a body of heated water and the outlet conduit is adapted to be connected to the inlet of a discharge pump, whereby due to water being sucked through the humidifier by the pump the water surrounding the air-transmitting fibers applies a negative pressure to the exterior of the fibers.

In preferred embodiments the air flow resistance value R is in the range between 850 and 2200, (corresponding to the resistance respectively of 9 and 7 mm standard endotracheal tubes), the presently preferred standard being R = 1300 (the resistance of an 8 mm standard endotracheal tube). For fibers of constant diameter, $R = \frac{L}{D^4} \times \frac{1}{N}$, where L is the air-transmitting length in inches, D is the internal diameter of the fibers in inches and N is the number of fibers.

Drawings

Fig. 1 is a longitudinal cross-sectional view of the preferred embodiment;

Fig. 2 is a transverse cross-sectional view of the embodiment taken on line 2-2 (omitting the fibers) and showing a closed mushroom valve in cross-section, while

Fig. 2a is a view of the mushroom valve when open;

Fig. 3 is a partial transverse cross-sectional view taken on line 3-3 of Fig. 1, on a magnified scale;

Fig. 4 is a longitudinal cross-sectional view on magnified scale taken on line 4-4 of Fig. 3;

Fig. 5 is a perspective view showing the embodiment in use with a patient; and

Fig. 6 is a diagrammatic view of the flow arrangement for air to be humidified and the negative pressure water.

Description of Preferred Embodiment

Referring to Figs. 1-4 the medical humidifier 50 comprises a bundle 10 of straight, elongated fibers, made of a substance (glycerinized polysulfone) which is permeable to water vapor and impermeable to water. The fiber bundle is loosely arranged in its major mid-portion 12 to provide water flow passages 13 (Figs. 3 and 4) over the exterior of the fibers, while the end portions 14 and 16 of the bundle are potted (bonded together) in water-impermeable bonding material 18 (epoxy). Similarly the sides of the potted end portions 14,16, are joined to end portions of chamber 20 defined by a rigid cylindrical wall (high density polystyrene). Between these ends the housing defines a water chamber capable of withstanding negative pressure. End caps 22 and 24 are provided at the respective ends of the housing, terminating in tapered external members 28. These serve as standard male breathing circuit connectors for insertion into mating female connectors or hose.

The humidifier unit is connected in any suitable respiratory flow path. In Fig. 5 the humidifier is shown in the inhalation leg from the respirator to a patient, with a respirator controlled exhalation valve 31 at the end of a Y connector exhausting to ambient.

As shown in Fig. 1, the end caps 22 and 24 each provide open spaces 30 and 32 beyond the ends of the fiber bundle, to define inlet and outlet air plenums. Air from the respirator 36 in Fig. 5 enters the male connector 28 at Fig. 1 at the right

hand side, fills inlet air plenum 30 and is there distributed across the end face of the fiber bundle, where it splits, to enter the numerous hollow fibers as filaments of air flow. These proceed through the fibers under the pressure of the respirator, exiting into outlet air plenum 32 on the left hand side of Fig. 1 where they rejoin. The nified flow proceeds through the connector to the patient.

The water chamber 20 has water inlet and outlet connectors 21, 23 (of different configuration to avoid mix-up) at the right and left hand sides of Fig. 1 respectively. These connectors and the conduits, 21a, 23a are also of sufficiently rigid material to withstand negative pressure. Inlet conduit 21a extends to a water reservoir 40 (Fig. 6) where the end is submerged in water. A heater element 42 maintains the water at the desired temperature under the control of probe 41 and thermostatic control swich 43. The water outlet conduit 23a is connected to the inlet of discharge pump P which discharges excess water into the reservoir 40. Water is drawn by the pump through the inlet 21a and through the space between the loosely nested fibers, thus filling the entire free volume of chamber 20 with water under negative pressure, e.g. - 2 psig. The water is drawn through discharge conduit 23a under the pull of discharge pump P.

A positive pressure relief valve 60 (Fig. 2) is incorporated in the wall of the housing. As shown in Figs. 2 and 2a, this valve is of the so-called, well-known mushroom type.

It comprises a leaflet 62 overlying relief holes 64 which extend from the interior of the chamber 20 to the atmosphere. A stem 66 is integrally joined to leaflet 62 and ends in enlarged inward end 58 which is larger than the passage through which the stem 62 extends and therefore holds the leaflet in place. Under negative water pressure conditions as shown in Fig. 2 the leaflet seals the passages 64. However referring to the magnified view of Fig. 2a, in the event that positive pressure should accidently be applied to the water volume of chamber 20, this positive pressure acts through the passage 64 to deflect the leaflet 62 to allow escape of liquid until the positive pressure is relieved.

The fibers have internal diameter of .060 inch and wall thickness .005 in. They are glycerinized to make them hydrophyllic by being immersed in glycerine during spinning of the fibers, in a stage while the polysulfone is still soft (as produced by Amicon Corporation).

The fibers are 3 inches in length with 3/8 to 1/2 inch of each end sealed in the potting material, resulting in an effective vapor-transmitting length between the ends in the range of 2 and 2 1/4 inch.

In this embodiment 178 of the fibers are nested together and provide an aggregate vapor transmitting area in the range of 67 to 84 in^2, depending upon the length of the potted end regions, and a capacity to humidify ambient air to saturation at 98.6°F at air flow rates between about 85 and 95 liters/min.

The flow resistance of this nested fiber module is represented by the figure of merit value $R = \frac{L}{D^4} \times \frac{1}{N} = 1300$ where L is the air transmitting (overall) length of the fibers in inches, D is the internal diameter of the fibers in inches and N is the number of fibers. Using this module an air flow of 300 liters/min. is achievable with an air pressure drop of 5cm. H_2O from end to end of the hollow fibers.

This provides an air flow resistance that is equivalent to the resistance of a standard 8 millimeter endotracheal tube. By observing this standard, the humidifier can be placed in any of the variety of respirator circuits and flow paths and indeed the patient can spontaneously inhale through it with no assistance of a respirator.

Suitable air flow characteristics in a practical, compact module are preferably achieved with fibers ranging in internal diameter upwards from .050 inch to about .070 inch, the length of the fibers being dependent upon their diameter and upon the number N of the fibers to be employed. The number N is also dependent upon the specific vapor transmitting characteristic of the fiber material and wall thickness selected. In some instances long modules may be convenient and in that case even larger bore fibers may be employed.

The glycerinized fibers have the advantage of high vapor rate transmission and long dry shelf life and when used with the positive pressure relief valve, offer a fail-safe operation. Where even further safety is desired it is possible to use fibers which are more immune to transmission of liquid water even in the event of accidental application of positive pressure to the water chamber. In this case preferably the fibers are produced to the hardened stage as hydrophobic polysulfone fibers and are subsequently treated with a wetting agent such as sodium sulfo succinate (stool softener marketed by Mead Johnson) and/or with glycerine. In this case, because of the added protection offered by the fibers it is in principle possible to omit the positive water pressure relief valve, but the valve is still preferred to maximize the safety of the device, particularly in view of the relatively larger number of fibers which are used when using material of the somewhat less vapor transmitting capability. The same is true if the fibers are formed of acrylic co-polymers such as the XM formulation manufactured by Amicon Corporation.

The water chamber 20 can advantageously be formed by injection molding of any suitable rigid plastic used in medical appliances, for instance the high impact polystyrene, mentioned above. The end caps, including the connectors, and defining the air plenums, can be of the same or similar material and can for instance be solvent-bonded to the exterior of the housing 20 in the manner shown. In a typical construction the assembly of fibers, having a length longer than the housing, is inserted loosely in the housing, and the potting material, epoxy or others such as silicone rubber is introduced in the end regions, through capillary action along the fibers, sometimes assisted by centrifugal force. After the potting material is set, the extreme ends of the matrix of potting material and hollow fibers can be sliced, as with a knife, flush with the ends of the housing 20, to provide a smooth end face with the fiber ends open to transmit air. The resulting bundle of fibers can readily provide a diffusion wall surface area of the order of .5 feet, effective to humidify an aggregate air flow volume of the order of 50 to 75 liters per minute at the instant of peak flow during the respirator cycle.

Operation

Referring to the figures the gross stream of inlet air A, Fig. 1, from the respirator 36 (Fig. 6) is divided into air stream filaments B_1, B_2, etc. in Figs. 3 and 4 by the many fiber of the nest. The heated water, as indicated diagrammatically in Figs. 3 and 4, flows over the exterior of these fibers while water vapor produced by this water supply permeates the thin walls of the fibers, in opposition to the pressure differential, and humidifies the dry air filaments. The air stream filaments B_1, B_2, etc. after transitting the length of the fibers 12 are humidified to saturation at body temperature. The air filaments are then restored to a unified air flow C in the discharge plenu 32, which proceeds into the patient.

In a typical operation the respirator 36 of Fig. 5 operates as an open cycle system in which exhaled air is discharged to the atmosphere through exhalation valve 31. During th inspiration phase of the cycle the respirator gradually increases the pressure on conduit 54, supplying air through the humidifier 50 to the end of endotracheal tube 52 inserted into the airway of the patient. The valve 31 in the discharge leg 56 of the Y fitting is closed during this phase by a control line from the respirator, hence all air flow from the respirator is channeled through the humidifier 50 and into the patient.

During the expiration phase the patient exhales spontaneously. At this time valve 31 is released by the control line from the respirator to relieve the exhaled air to the atmosphere. A check valve, not shown, during the expiration phase prevents back-flow of exhaled air through the humidifier.

The hollow fibers being subjected to a decreasing pressure gradient from inside to outside take advantage of the substantial tensile strength of the wall of the fibers to ensure that they do not collapse. With the water under vacuum, little liquid water will enter the airway in the event of accidental rupture of a fiber wall. Even if a reverse pressure differential is encountered as by accidental misconnection of the pump, it is important to realize that the hollow fibers, due to their small size, demonstrate a sufficient degree of structural rigidity to resist crushing that would block the air flow to the patient.

By use of the particular fibers described, a sufficient vapor-transmitting surface area to volume ratio is obtained while still obtaining sufficient air-transmitting capacity to enable a small number of fibers, in the preferred range of 100 to 200, to be employed. The feature permits a large diffusion surface to be obtained in a small geometric volume. Such small size permits the humidifier to be mounted close to the patient, and permits it to be an inexpensive disposable component, to be replaced periodically, for instance once a day, at the same time

that the hoses are ordinarily changed. The construction leads to the possibility of extending the time between sterilizations of the inlet hose, from the respirator to the humidifier, owing to the fact that it now does not contain moist warm air and therefore is not a place where bacteria multiply rapidly.

Certain features of the invention are useful without other features of the invention. For instance a humidifier using static water at atmospheric pressure as by use of a collapsible outer wall can in certain instances be used to good effect with the specified fiber construction.

What is claimed is:

1. A humidifier for a respiratory flow path connected directly to the air way of a patient, through which life-supporting air can be channeled, comprising a compact nest of discrete, elongated air-transmitting hollow relatively large bore, relatively thin wall fibers connected in parallel by inlet and outlet connections and having walls of substance permeable to water vapor and impermeable under operating conditions to liquid water, rigid means defining a relatively negative-pressure water-filled chamber surrounding the effective length of the fibers, the fibers adapted to divide dry inhalation air for a patient which enters said inlet connection into a series of air-flow filaments for humidification by water vapor that permeates the wall of the fibers from the surrounding relatively negative-pressure water, the fibers being provided in size and number sufficient to freely pass under normal air-flow conditions an aggregate air flow volume corresponding to the life-supporting need of the patient, and to provide effective fiber surface area sized to pass water vapor sufficient to humidify air at normal flow rates substantially to saturation from said relatively negative-pressure water heated to about body temperature, said outlet connection arranged to collect the thus humidified filaments of air and direct the unified flow into the patient, whereby said humidifier can provide full humidification of air directed into a patient in a practical, fail-safe, low flow resistance compact unit that can be disposable.

2. The humidifier of claim 1 wherein said fibers have an aggregate capacity to humidify to saturation at 98.6°F ambient air at flow rate of the order of 50 liters per minute or higher.

3. The humidifier of claim 1 wherein said fibers define an aggregate effective water-vapor transmitting surface area of the order of about one half square foot.

4. The humidifier of claim 1 wherein said hollow fibers have a wall thickness that is 10% or less of the internal diameter of said fibers.

5. The humidifier of claim 1, 2, 3 or 4 wherein said hollow fibers have an internal diameter greater than .050 inch.

6. The humidifier of claim 5 wherein said hollow fibers have an internal diameter less than .070 inch.

7. The humidifier of claim 1, 2, 3 or 4 wherein the substance of said fibers has dry stability and a transmission characteristic of the order of one pound of water per square foot of fiber wall area per .005 inch wall thickness, with water at 37.5°C, at 2 psi negative pressure on the exterior of said fibers and with a flow of anhydrous oxygen at an aggregate rate of 200 liters per minute flowing in parallel through a nest of fibers of 5 inches length.

8. The humidifier of claim 7 wherein said hollow fibers have an internal diameter in the range of about .050 inch to .070 inch.

9. The humidifier of claim 1 or 17 wherein the substance of said fibers is selected from the group consisting of polysulfones and acrylic copolymers.

10. The humidifier of claim 9 wherein the substance of said fibers incorporates a wetting agent.

11. The humidifier of claim 10 wherein said wetting agent is glycerine.

12. The humidifier of claim 10 wherein said wetting agent is sodium sulfo succinate.

13. The humidifier of claim 1 or 17 wherein a pressure relief valve is connected to the water side of said unit, constructed to vent to the atmosphere in the event of any condition tending to produce a positive pressure in the water surrounding the fibers.

14. The humidifier of claim 1 or 13 wherein there are water inlet and outlet conduits connected to provide a flow of heated water to the outside of said fibers, said conduits being rigid to resist collapse when vacuum is applied, said inlet conduit adapted to be connected to a body of heated water and said outlet conduit adapted to be connected to the inlet of a discharge pump, whereby due to water being sucked through said humidifier by said pump the water surrounding said air-transmittin fibers, can apply a negative pressure to the outside of said fibers.

15. The humidifier of claim 1 or 17 where said nest of fibers has an aggregate air flow figure of moist resistance value R between about 850 and 2200 where $R = \frac{L}{D^4} \times \frac{1}{N}$, L and D are length and internal diameter of fibers in inches, and N is the number of fibers.

16. The humidifier of claim 15 wherein R is about 1300 and N is in the range of 100 to 200.

17. A humidifier for a respiratory flow path connected directly to the air way of a patient, through which life-supporting air can be channeled, comprising a compact nest of discrete, elongated air-transmitting hollow relatively large bore, relatively thin wall fibers connected in parallel by inlet and outlet connections and having walls of substance permeable to water vapor and impermeable under operating conditions to liquid water, means defining a water-filled chamber surrounding the effective length of the fibers, the fibers adapted to divide dry inhalation air for a patient which enters said inlet connection into a series of air-flow filaments for humidification by water vapor that permeates the wall of the fibers from the surrounding water, the fibers being provided in size and number sufficient to freely pass under normal air-flow conditions an aggregate air flow volume corresponding to the life-supporting need of the patient, and to provide effective fiber surface area sized to pass water vapor sufficient to humidify air at normal flow rates substantially to saturation from said water heated to about body temperature, said outlet connection arranged to collect the thus humidified filaments of air and direct the unified flow into the patient, whereby said humidifier can provide full humidification of air directed into a patient in a practical, fail-safe, low flow resistance compact unit that can be disposable, and further

Claim 17, cont'd.

characterized in that said fibers have an aggregate air flow capacity of the order between about 180 and 450 liters per minute with a pressure drop of 5 cm H_2O from end to end of the hollow fibers, said fibers define an aggregate effective water-vapor transmitting surface area of the order of about one half square foot, said hollow fibers have a wall thickness that is 10% or less of the internal diameter of said fibers, and said hollow fibers have an internal diameter greater than .050 inch.

18. The humidifier of claim 5 wherein said hollow fibers have an internal diameter less than .070 inch.

19. The humidifier of claim 17 or 18 wherein the substance of said fibers has dry stability and a transmission characteristic of the order of one pound of water per square foot of fiber wall area per .005 inch wall thickness, with water at 37.5°C, at 2 psi negative pressure on the exterior of said fibers and with a flow of anhydrous oxygen at an aggregate rate of 200 liters per minute flowing in parallel through a nest of fibers of 5 inches length.

20. The humidifier of claim 17 or 18 wherein the substance of said fibers is selected from the group consisting of polysulfones and acrylic copolymers.

21. The humidifier of claim 1, 2, 3 or 4 wherein said fibers have an aggregate air flow capacity between about 180 and 450 liters per minute with an air pressure drop of 5 cm H_2O from end to end of the hollow fibers.

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FIG 1

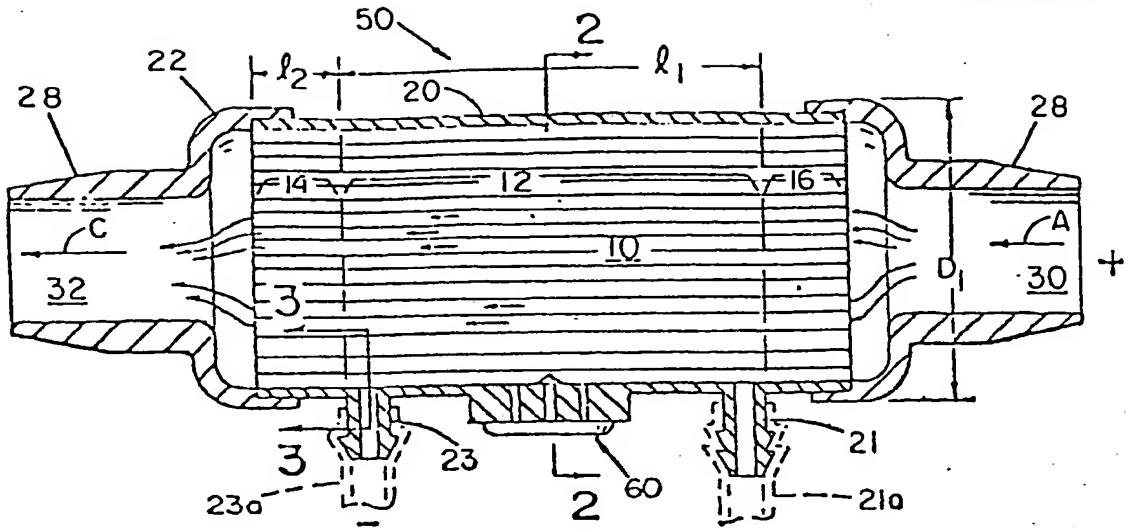
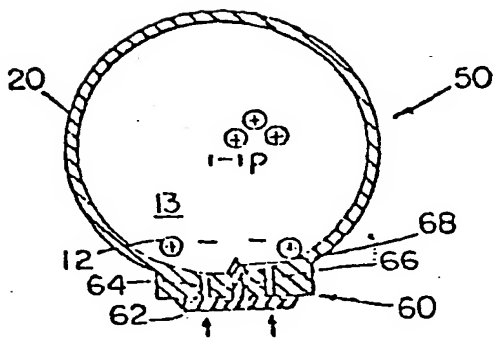


FIG 2



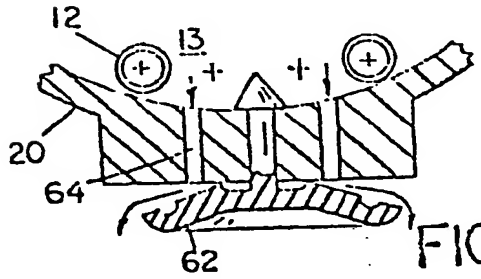


FIG 2a

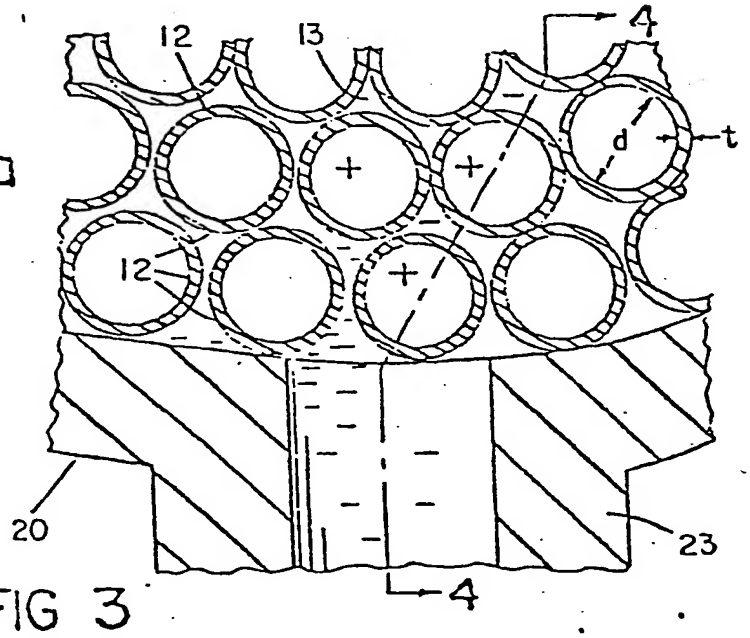


FIG 3

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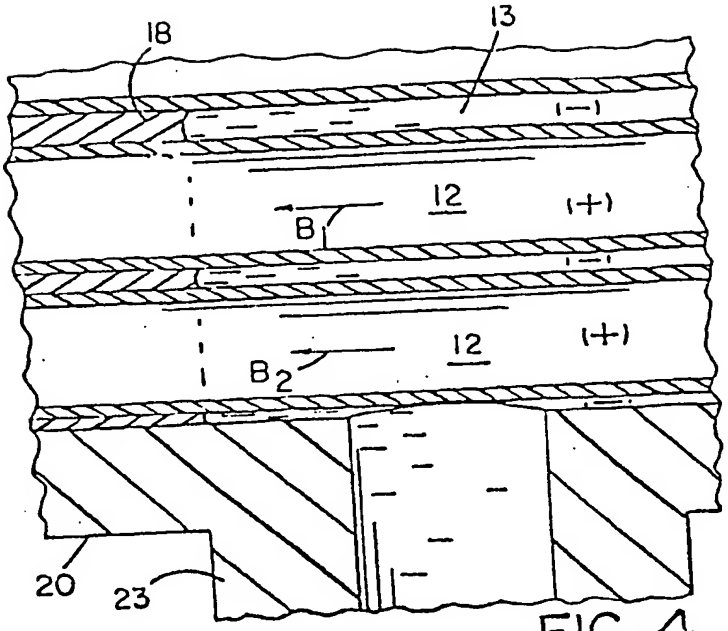
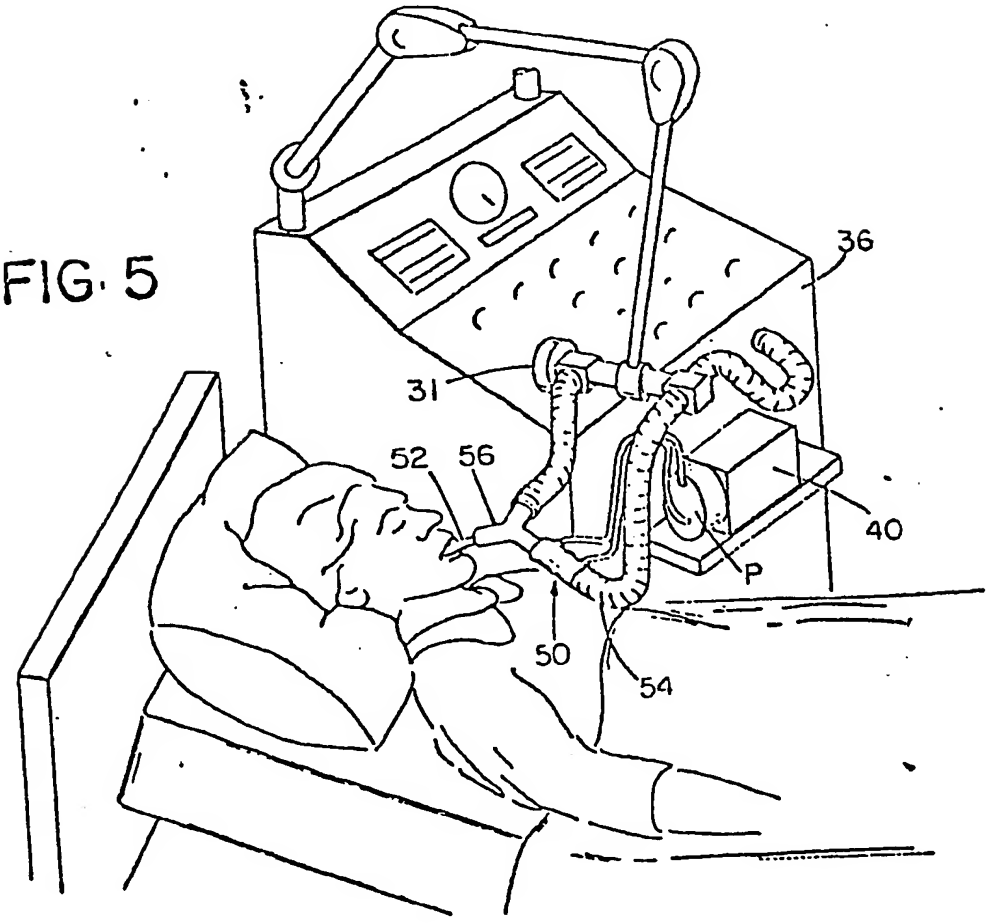


FIG 4

FIG. 5



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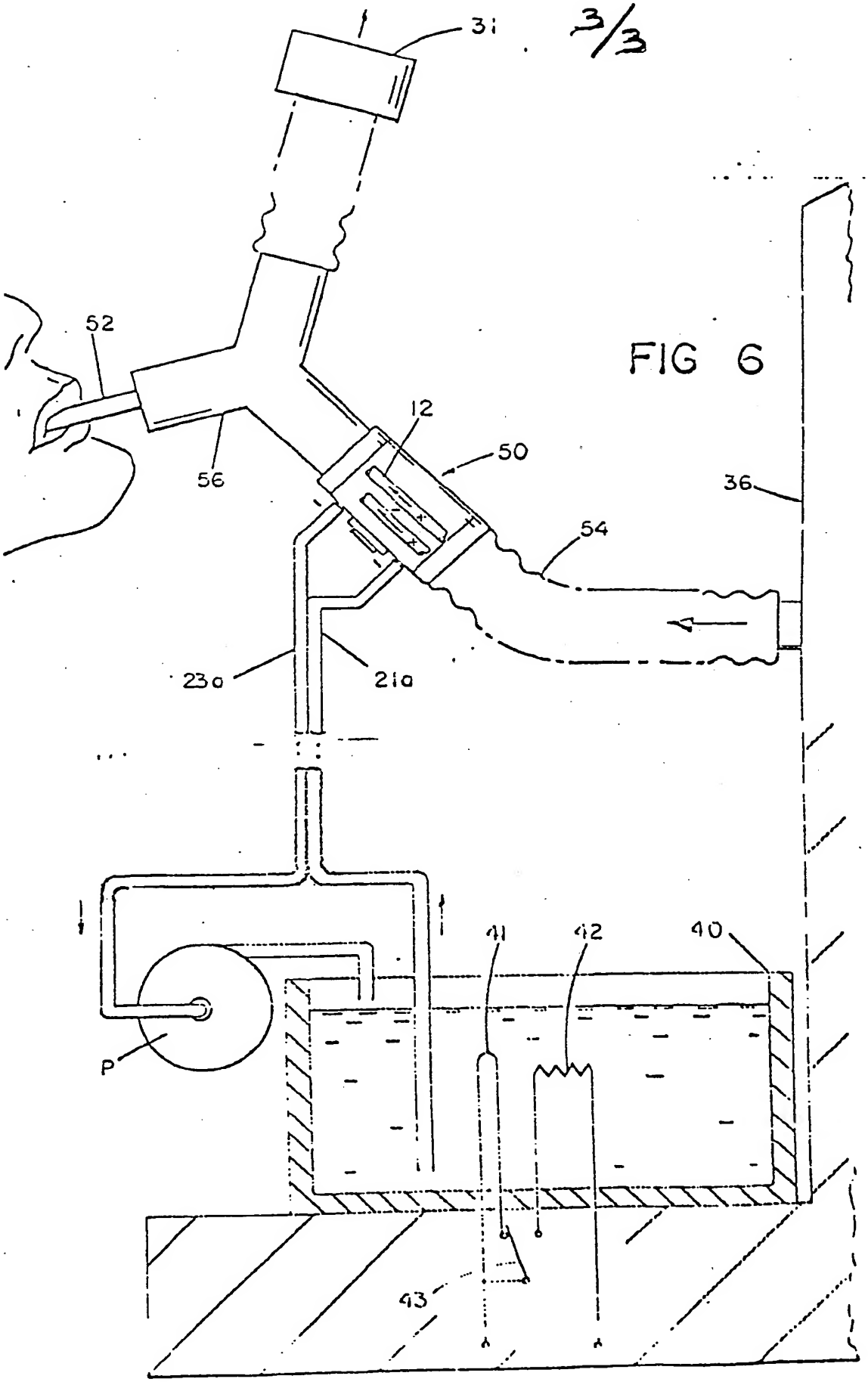

FIG 6

0009543
Application number

European Patent Office

EUROPEAN SEARCH REPORT

EP 79 102 287.4

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
X	DE - A1 - 2 617 985 (DRÄGERWERK AG) * pages 7 and 8; fig. 1 *	1
D	US - A - 4 086 305 (DRÄGERWERK AG) * column 3, line 10 to column 4, line 33; fig. 1 *	1
D	US - A - 4 010 748 (DRÄGERWERK AG) * column 4, lines 5 to 52; fig. 1 *	1
D	US - A - 4 098 852 (RHONE-POULENC) * column 3, lines 64 and 65; fig. 1 *	9,20
P	DE - A1 - 2 703 892 (DRÄGERWERK AG) * page 6; fig. 1 *	1

CLASSIFICATION OF THE APPLICATION (Int. Cl.³)

A 61 M 16/00

TECHNICAL FIELDS SEARCHED (Int.Cl.³)

A 61 M 15/00
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CATEGORY OF CITED DOCUMENTS

X: particularly relevant
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X The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Berlin	02-11-1979	HOFFMANN

EPO Form 1503.1 06.78